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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,750	09/05/2003	Johnson E. Goode	P0011367.00	9063

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EXAMINER	
MEHTA, BHISMA	

ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
12/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/656,750	GOODE ET AL.	
	Examiner	Art Unit	
	BHISMA MEHTA	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 July 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings were received on July 21 2008. These drawings are acceptable.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to disclose fails to disclose the thru lumen tubing forming a single lumen. The specification fails to disclose the medical therapy delivery device having an anchoring device positioned along a distal end of the second portion and fixedly engaged with the manipulator wire. Applicant's arguments in lines 1-9 of page 13 have been considered but are not deemed persuasive. There is no disclosure in the specification of an anchoring device. Paragraph 30 of the specification discloses an anchoring band. It is suggested that the specification and/or claims be amended so that the language used in the claims corresponds to the specific language in the specification. Therefore, it is suggested that either the term "anchoring band" be used in the claims or the specification be amended to indicate that the anchoring band 160 is an anchoring device.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 6-12, 16, 19, 20, 22, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle (U.S. Patent No. 4,748,969) in view of Truckai (U.S. Patent No. 5,397,304).

Wardle discloses a medical therapy delivery device having a shaft with a first portion (14) and a second portion (12). As shown in Figure 4, a deflectable tip (48) extends distally from the second portion and has a tapered portion and a tip lumen (shown at 58). The device also includes a manipulator wire (40) that extends through the shaft and a thru lumen tubing (32) having a thru lumen. In Figures 2 and 5, the outer layer of the shaft forms a single shaft lumen having a first lumen portion (shown at 28 in Figure 2 and at 6 in Figure 5) positioned about the thru lumen tubing and a second lumen portion (shown above the portion shown at 28 in Figure 2 and above the portion shown at 6 in Figure 5) having a first side wall, a second side wall, and a bottom side wall which position the manipulator wire within the second lumen portion. The second lumen portion is offset from and in fluid communication with the first lumen portion. As to claim 11, as shown in Figure 4, an anchoring device or band (72) is positioned along a distal end of the second portion and is fixedly engaged with the manipulator wire (40). Also shown is the manipulator wire (40) that extends through the transition lumen of the transition tubing (30). As to claim 16, Wardle discloses a portion (50) of the thru lumen tubing is capable of sliding within the shaft during deflection of the second portion of the shaft (lines 40-63 of column 7). As to claim 19, in Figure 5, Wardle shows the first and

second flanges as claimed. As to claim 20, Figures 2 and 5 shows the thru lumen tubing (32), the first side wall, the second side wall, and the bottom side wall positioning the transition tubing (30) within the second lumen portion. As to claim 22, the first lumen portion is generally semi-circular in shape and the second lumen portion is generally rectangular in shape. As to claim 41, the thru lumen tubing (32) forms a single lumen.

Wardle discloses the invention substantially as claimed. Even though Wardle discloses the second portion (12) to be deflectable relative to the first portion (14) and the first portion to be flexible only sufficiently such that the first portion can follow the contours of the passages through which the device is being entered, Wardle does not disclose the first portion as being non-deflectable and the transition tubing being formed of a polyimide material having a durometer reading of 86D. Wardle is also silent on the thru lumen being formed by a polyether block amide material having a durometer reading of 72D. In Figures 1 and 2, Truckai shows a steerable medical device having a first non-deflectable portion (10) and a second portion (16) which is deflectable relative to the first portion. The device also has a thru lumen formed by a PEBA material with a durometer in the range of 30D to 60D and a polyimide transition tubing (58) through which a manipulator wire extends. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the first portion of Wardle as a non-deflectable as taught by Truckai as both Wardle and Truckai disclose steerable devices and Truckai teaches that it is well known to provide steerable devices with a non-deflectable first portion to allow for the accurate manipulation of the deflectable

second portion. It also would have been obvious to one having ordinary skill in the art at the time the invention was made to make the thru lumen of Wardle from a PEBA material as taught by Truckai as both Wardle and Truckai disclose steerable devices having a thru lumen and Truckai teaches that it is well known to use PEBA for the material of the thru lumen. As to the limitation of the thru lumen tubing being formed polyether block amide having a durometer reading of 72D in claim 7, Truckai does disclose polyether block amide as a suitable material for a medical device and the parameter of the durometer reading of the thru lumen tubing is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. It also would have been obvious to one having ordinary skill in the art at the time the invention was made to make the transition tubing of Wardle from a polyimide material as taught by Truckai as both Wardle and Truckai disclose steerable devices having a transition tubing through which a manipulator wire extends and Truckai teaches that it would be advantageous to make the transition tubing from polyimide to provide lateral and torsional stiffness to the deflectable tip. As to the limitation of the polyimide material having a durometer reading of 86D, the parameter of the durometer reading is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

As to claims 6, and 8-10, Wardle discloses the invention substantially as claimed. Wardle discloses that the tip includes a distal opening and, in Figure 4, the distance between the outer wall and inner wall gradually decreases between the proximal end

and the distal end of the tapered portion. However, Wardle does not disclose the thicknesses of the walls of the deflectable tip or the diameters of the various components of the medical device. However, these parameters are deemed matters of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation, in determining optimum results.

5. Claims 2, 3, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle and Truckai as applied to claims 1 and 11 above, and further in view of Hayzelden (U.S. Patent Application Publication No. 2003/0050598).

Wardle and Truckai disclose the invention substantially as claimed. Even though Wardle teaches in line 61 of column 5 to line 14 of column 6 that the outer layer (66) is formed of a polymer and contain a stainless steel braiding (67) to provide torsional stiffness to the shaft, Wardle is silent on the outer layer being specifically formed of polyether block amide and including a stainless steel braiding and having a durometer reading of 72D along the first portion and being non-braided and having a durometer reading of 40D along the second portion. In Figures 1-3, Hayzelden shows the outer layer (42) of a medical device having a first portion (12) made of a high durometer (such as 63D) polyether block amide with a stainless steel braiding (44) and a second non-braided portion (14) and teach that the braiding provides reinforcement to the first portion. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the outer layer of Wardle with a polyether block amide as taught by Hayzelden as both Wardle and Hayzelden teach that it is well known to use polymer materials for medical devices and Hayzelden teaches the use of polymer

materials such as polyether block amide. It would also have been obvious to one having ordinary skill in the art at the time the invention was made to make the first portion of the outer layer of Wardle with a high durometer (such as 63D) polyether block amide with a stainless steel braiding as taught by Hayzelden as both Wardle and Hayzelden disclose devices having a deflectable second portion and Hayzelden teaches that it would be advantageous to reinforce the first portion to allow for the proper deflection of the second portion when it is being used in a surgical procedure. As to the limitation of the first portion having a durometer reading of 72D and the second portion having a durometer reading of 40D, in lines 31-63 of column 16, Hayzelden teaches that the first portion (12) would have a higher durometer reading than the second portion (14) and that the second portion (14) is made to be sufficiently resilient or flexible and that material modifications can be made to suit the particular needs of the user. Therefore, the parameter of the durometer readings of the first portion and the second portion is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. As to the limitation of the transition tubing having a length of approximately one inch in claim 18, the parameters of length is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle and Truckai as applied to claim 1 above, and further in view of Hobbs et al (U.S. Patent No. 5,584,821).

Wardle and Truckai disclose the invention substantially as claimed. However, Wardle is silent on the deflectable tip being formed of a radio opaque and echo-genic polymer material. Hobbs et al disclose a medical device having a deflectable tip (16) made of a polyether block amide material loaded with tungsten. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the deflectable tip of Wardle from a radio opaque and echo-genic polymer material such as a polyether block amide material loaded with tungsten as taught by Hobbs et al as both Wardle and Hobbs et al teach advancing a medical device in narrow vessels or cavities and Hobbs et al teach that it is beneficial to have a tip that allow the distal end of the medical device to be seen by the user as it is advanced in the body.

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle, Truckai, and Hobbs et al as applied to claim 4 above, and further in view of Kousai et al (U.S. Patent No. 4,778,455).

Wardle, Truckai, and Hobbs et al disclose the invention substantially as claimed. Even though Hobbs et al disclose a medical device having a deflectable tip (16) made of a polyether block amide material loaded with tungsten, Hobbs et al are silent on the deflectable tip being formed of a radio opaque and echo-genic polymer material such as tungsten carbide and having a durometer of 35D. Kousai et al disclose a medical device having a tip (1) made of a polymer material loaded with tungsten carbide. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the tungsten of Hobbs et al with tungsten carbide as taught by

Kousai et al as both Hobbs et al and Kousai et al teach advancing a medical device in narrow vessels or cavities and Kousai et al teach that it is well known to use tungsten or tungsten carbide in the distal tip to allow the distal end of the medical device to be seen by the user as it is advanced in the body. As to the limitation of the PEBA material having a durometer reading of 35D, the parameter of the durometer reading is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

8. Claims 13-15, 17, 21, 23-26, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle and Truckai as applied to claims 11and 1 above, and further in view of Ponzi (U.S. Patent No. 5,897,529).

Wardle and Truckai disclose the invention substantially as claimed as discussed above. Even though Wardle discloses the medical device having a compressible member through which the manipulator wire extends and the distal end of the compressible member fixedly engaged with the outer layer (lines 15-40, column 6), Wardle is silent on the specifics of the compressible member being positioned between the distal end of the transition tubing and the anchoring device or band and being free to move relative to the manipulator wire and the shaft during deflection of the second portion. In Figure 2, Ponzi shows a steerable medical device having a compressible member (44) through which a manipulator wire (42) extends. In lines 14-45 of column 6, Ponzi teaches that the compressible member is anchored at its proximal end and distal end thus allowing it to move freely relative to the manipulator wire and the shaft during defection. The wire preferably has a diameter ranging from about 0.006 to 0.010

inches. The inner diameter of the compressible member is preferably slightly larger than the diameter of the manipulator wire. It would have been obvious to one having ordinary skill in the art at the time the invention was made to position the compressible member of Wardle between the distal end of the transition tubing and the anchoring device or band where the distal end of the compressible member is fixedly engaged with the outer layer so that the compressible member can move freely as taught by Ponzi as both Wardle and Ponzi disclose steerable devices having a compressible member through which a manipulator wire extends and Ponzi teaches that it would be advantageous to have a compressible member to provide flexibility to the deflectable portion of the steerable device. As the limitation of the diameters of the compressible members in claim 14, the parameter of diameters is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. As to the limitation of the transition tubing having a stiffness greater than the compressible member in claim 17, it would be obvious to one having ordinary skill in the art at the time the invention was made that transition tubing of Wardle would be stiffer than the flexible compressible member of Ponzi as the compressible member is in the second deflectable portion of the shaft. As to claim 25, Wardle, Truckai and Ponzi do not disclose the specifically claimed diameters of the various components of the medical device. However, these parameters are deemed matters of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation, in determining optimum results. As to claim 40, the deflectable tip (48) is considered to be passively deflectable relative to the second portion and the

thru lumen tubing (32) has an outer wall as shown in Figure 4. The outer layer of the shaft along the first portion (12) is of uniform thickness and has an inner wall which forms the single shaft lumen positioned about the thru lumen tubing (32) and the manipulator wire (40) where the manipulator wire is advanceable and retractable between an inner wall of the outer layer and an outer wall of the thru lumen tubing. Figures 2 and 5 shows the outer layer along the second portion of the shaft where the outer layer forms the first lumen portion and the second lumen portion. The transition tubing (30) is positioned within the second lumen portion and extends between a proximal end of the second portion to a point along the second portion of the shaft as shown in Figure 3.

9. Claims 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle, Truckai, and Ponzi as applied to claim 26 above, and further in view of Hayzelden (U.S. Patent Application Publication No. 2003/0050598).

Wardle, Truckai, and Ponzi disclose the invention substantially as claimed. Even though Wardle teaches in line 61 of column 5 to line 14 of column 6 that the outer layer (66) is formed of a polymer and contain a stainless steel braiding (67) to provide torsional stiffness to the shaft, Wardle is silent on the outer layer being specifically formed of polyether block amide and including a stainless steel braiding and having a durometer reading of 72D along the first portion and being non-braided and having a durometer reading of 40D along the second portion. In Figures 1-3, Hayzelden shows the outer layer (42) of a medical device having a first portion (12) made of a high durometer (such as 63D) polyether block amide with a stainless steel braiding (44) and

a second non-braided portion (14) and teach that the braiding provides reinforcement to the first portion. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the outer layer of Wardle with a polyether block amide as taught by Hayzelden as both Wardle and Hayzelden teach that it is well known to use polymer materials for medical devices and Hayzelden teaches the use of polymer materials such as polyether block amide. It would also have been obvious to one having ordinary skill in the art at the time the invention was made to make the first portion of the outer layer of Wardle with a high durometer (such as 63D) polyether block amide with a stainless steel braiding as taught by Hayzelden as both Wardle and Hayzelden disclose devices having a deflectable second portion and Hayzelden teaches that it would be advantageous to reinforce the first portion to allow for the proper deflection of the second portion when it is being used in a surgical procedure. As to the limitation of the first portion having a durometer reading of 72D and the second portion having a durometer reading of 40D, in lines 31-63 of column 16, Hayzelden teaches that the first portion (12) would have a higher durometer reading than the second portion (14) and that the second portion (14) is made to be sufficiently resilient or flexible and that material modifications can be made to suit the particular needs of the user. Therefore, the parameter of the durometer readings of the first portion and the second portion is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

10. Claims 28-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle, Truckai, Ponzi, and Hayzelden as applied to claim 27 above, and further in view of Kousai et al (U.S. Patent No. 4,778,455).

Wardle, Truckai, Ponzi, and Hayzelden disclose the invention substantially as claimed. Even though Hayzelden discloses a medical device made of a polymer such as PEBA, Wardle, Truckai, Ponzi, and Hayzelden are silent on the deflectable tip being formed of a radio opaque and echo-genic polymer material such as tungsten carbide and having a durometer of 35D. Kousai et al disclose a medical device having a tip (1) made of a polymer material loaded with tungsten carbide. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the deflectable tip of Wardle with tungsten carbide as taught by Kousai et al as Kousai et al teach that it is well known to use tungsten carbide in the distal tip to allow the distal end of the medical device to be seen by the user as it is advanced in the body. As to the limitation of the PEBA material having a durometer reading of 35D, the parameter of the durometer reading is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. As to the limitation of the polyimide material having a durometer reading of 86D, the parameter of the durometer reading is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. As to the limitation of the diameters of the compressible members in claim 35, to the limitation of the diameters of the various components of the medical device in claims 36 and 37, and to the limitation of the transition tubing having a

length of approximately one inch in claim 39, the parameters of diameter and length are deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

Response to Arguments

11. Applicant's arguments, see lines 7-26 of page 12, filed July 21 2008, with respect to the objection to the declaration have been fully considered and are persuasive. The objection of the declaration has been withdrawn and the declaration filed September 5 2003 has been determined to be acceptable.

12. Applicant's arguments filed July 21 2008 have been fully considered but they are not persuasive. The outer layer (66) of the shaft does form a single shaft lumen which is the lumen containing the braiding (67) (Figure 5). In the single shaft lumen, there is a first lumen portion (shown at 28 in Figure 2 and at 6 in Figure 5) which is positioned about the thru lumen tubing and a second lumen portion (shown above the portion shown at 28 in Figure 2 and above the portion shown at 6 in Figure 5) having a first side wall, a second side wall, and a bottom side wall which position the manipulator wire within the second lumen portion. Therefore, the single shaft lumen of the outer layer (66) does have a first lumen portion and a second lumen portion. The second lumen portion is offset from the first lumen portion as the second lumen portion as seen in Figures 2 and 5. The second lumen portion is also considered to be in fluid communication with the first lumen portion as at least a section of the second lumen portion can be considered to be in fluid communication with at least a section of the first

lumen portion as seen in Figure 5. It should be noted that the first lumen portion and the second lumen portion have been interpreted as outer portions of the lumens (32) and (56).

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhisma Mehta/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767